REMARKS

In response to the Office Action mailed on June 4, 2004, Applicants submit the following Amendment and Response. Claims 59 and 76 have been amended. Claims 53-67, 69-72, 75-76, 80, and 83-85 remain pending. Claim 59 was amended to delete the word "carbon" and claim 76 was amended to correct the dependency. Therefore, these amendments are made without the addition of new matter.

Amendments to the Specification

Applicants have amended the specification to include passages from various provisional applications, which were expressly incorporated by reference in the current specification. (Page 10, lines 3-4) Support for these amendments can be found in provisional application serial no. 60/090,243, filed June 22, 1998, at e.g., page 6, lines 8-17; page 8, lines 3-8; page 8, lines 9-12; page 8, line 20 – page 9, line 7; page 10, lines 13-15; page 10, lines 21-22; and page 12, lines 15-16 (claim 10). Support can also be found in provisional application serial no. 60/114,863, filed January 6, 1999, at e.g., page 11, line 26 – page 12, line 9. Support can also be found in provisional application serial no. 60/117,421, filed January 27, 1999, at e.g., page 9, lines 11-15, page 12. Therefore, these amendments were made without the addition of new matter.

35 U.S.C. § 112

Claims 53-89 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to provide enablement for dictating the amount of time the bioabsorbable element remains at the site. (Office Action, page 2) Specifically, the examiner alleges that the specification does not disclose:

staying at the site for a predetermined amount of time to permit the relocation of the biopsy site; the marker interferes with the imaging of the surrounding tissue during a first time but not after a second time point; and a time frame of "2 weeks" as stated in claim 62.

Applicants respectfully assert that these elements are disclosed in the specification and the provisional applications, which are incorporated by reference and to which the current application claims priority. The relevant excerpts from the provisional applications have been added to the specification herewith. For example, in Application Serial No. 60/090,243 (hereinafter "the '243 application"), the specification describes how the device "will serve as a temporary marker for subsequent surgery .... The device would allow the surgeon to visually and tactilely locate the previously biopsied site. It is also an object of the present invention that the device be biodegradable and resorbable, allowing the device to gradually vanish in women with benign diagnoses, obviating the unneeded permanent metallic marker in the great majority of women undergoing breast biopsies." (the '243 application, page 6, lines 8-17). This passage has been added to the current specification by amendment (see page 2 of this paper). The '243 provisional application also discloses that "the device must not be resorbed so quickly that it is not palpable at the time of surgical wide excision in the case of a malignant diagnosis. ...Therefore, the device must not be significantly resorbed for at least **two weeks** after it is deployed or implanted within the breast." (emphasis added) (the '243 application, page 8, line 21 – page 9, line 3). This passage has been added to the current specification by amendment (see page 4 of this paper). In addition, the specification of the current application states that "the bioabsorbable material will typically be absorbed within about a month of placement." (page 3, lines 14-15).

Applicants respectfully assert that the above passages provide support for the detectable marker staying at the site for at least a predetermined first time period after introduction in order to permit detection. As stated above, the specification discloses that "the device must not be resorbed so quickly that it is not palpable at the time of surgical wide excision in the case of a malignant diagnosis. ... Therefore, the device must not be significantly resorbed for at least two weeks after it is deployed or implanted within the breast." (the '243 application, page 9, lines 1-3 and added by amendment to the current specification). Because the marker is bioresorbable, the marker will be absorbed over time. Therefore, after it is resorbed, it will not interfere with imaging of the tissue adjacent the site at a second predetermined time point because it will no longer be present at the site. The claimed feature of "staying at the site for a predetermined amount of time" is therefore an inherent property of the bioresorbable marker described in the present application.

The examiner asserts that the specification fails to disclose the use of a visualization means for the marker element, including a coloring means using dyes and carbon. Applicants respectfully assert that the visualization means is described in the specification at, e.g., page 4, lines 28-29 ("The visual detectability of the bioabsorbable element may be aided by the use of a **coloring agent**, such as methylene blue or some other **dye**." (emphasis added) Additionally, the '243 application discloses that "[i]t may be advantageous to enhance the visual detectability of the device by coloring it or causing it to contain a bioresorbable color such as methylene blue or other dye." ('243 application, page 8, lines 9-12). This passage has been added by amendment to the detailed description by amendment in the current paper (see page 5).

With regard to the rejection to "carbon," applicants have amended claim 59 to delete carbon. Therefore, this rejection is now moot.

The examiner alleges that the specification fails to disclose the use of a clearance delaying element using an encapsulating material. Applicants respectfully assert that support can be found in the '243 provisional application, which states "[b]ecause some materials may react with blood or other fluids before being completely deployed, a thin coating of a second material may be needed to permit the device to be completely deployed. It is anticipated that the second material would be rather quickly biodegradable, which would allow the first material to expand or react with body fluids soon after deployment." ('243 application, page 8 lines 3-8). Similarly, in Provisional Application Serial No. 60/114,863 (the '863 application), an encapsulating material is described on page 12, lines 7-9 ("One solution is to cover all or a portion of the marker device with a thin layer or film of bioresorbable material which does not immediately react with or absorb blood or body fluids.") Both of these excerpts have been incorporated into the current specification by amendment.

The examiner also alleges that the specification fails to disclose a marker comprising a dry powder, a sponge, a liquid, and collagenous material with radiographically imageable material attached to the marker. Insofar as this rejection pertains to "dry powder," although applicants believe that this is an obvious variation of the materials disclosed in the present specification and provisional applications, claim 68 was canceled in the previous response. With respect to the recitation of "a liquid," Applicants respectfully assert that support can be found in the current specification at, e.g., page 7, lines 5-6 ("bioabsorbable element 34 in its pre-delivery state within barrel 30 could be in a liquid or otherwise flowable form ..." (emphasis added)) Support can also be found in the '243 provisional application at, e.g., page 9, lines 14-16 ("the device will be inserted

through the biopsy needle and deployed within the recently biopsy site. [sic] This may be done by injecting, in the case or a liquid or semisolid material, ... (emphasis added)).

With respect to the recitation of the term "sponge," applicants respectfully submit that support for a detectable marker comprising a sponge can be found in the specification at, e.g., page 9, lines 4-8 ("While the bioabsorbable element is preferably made of collagen in one embodiment, the bioabsorbable element can include, for example, one or more of the following materials; polyactic [sic] and polyglycolic acids, polyorthoesters, resorbable silicones and urethanes, lipids, polysaccharides, starches, ceramics, polyamino acids, proteins, hydrogels and other gels, gelatins, polymers, cellulose, elastin, and the like.") Burbank et al. (USP 6,161,034), from which the pending claims were substantially copied, listed only collagenous or gelatinous materials (Col. 8, lines 5-10 and Col. 8, lines 31-45) The only instance where Burbank uses the term "sponge" is in the claims. Therefore, the term "sponge" must be read to encompass collagen materials. Applicants note that these same materials have been described in the current specification. If the term "sponge" is inherently supported by the written description of Burbank, then the same term must necessarily be described in the examples of bioabsorbable materials provided in the current application, which include collagen sponge. Moreover, Applicants respectfully argue that the examiner's rejection is improper under MPEP § 2307.2. If this rejection of applicants' claims is equally applicable to the patent claims of USP 6,161,034, then it is respectfully urged that the rejection requires the approval of the Group Director under MPEP § 2307.2. On the other hand, if the examiner does not consider the rejection to be applicable to the patent claims of USP 6,161,034, the examiner is respectfully requested to indicate as much in the next Office Action.

With respect to a marker comprising "collagenous material with radiographically imageable material attached to the marker," support for this embodiment can be found in the current specification at page 9, lines 4-5 ("the bioabsorbable element is preferably made of **collagen** in one embodiment ...." (emphasis added)). Support can also be found in the '243 provisional application at page 10, lines 18-22. "Collagen," of course, is a "collagenous material." Furthermore, support for the collagenous material with radiographically imageable material can be found in the specification at, e.g., page 4, lines 29-30 ("The radiographic detectability of the element may be enhanced by a radiopaque marker.") and page 8, lines 25-26 ("To facilitate the delivery, the bioabsorbable element may contain a radiopaque marker ..."). Support in the '243 provisional application can also be found at, e.g., page 7, lines 16-21 and page 8, lines 12-17.

With respect to a marker comprising ions, Applicants respectfully assert that support can be found in the present specification at, e.g. page 8, lines 7-13 ("The bioabsorbable element may be changed from its pre-delivery state to its post-delivery state in a variety of manners including ... by ionizing the bioabsorbable element, ... (emphasis added)). Applicants note that "ionizing the bioabsorbable element" would result in ions. Additionally, support can be found in the '243 provisional application at, e.g., page 8, lines 16-17 ("For the device to be detected by mammography, it would have to be radiopaque and probably contain iodine.") This passage has been added to the current specification by amendment herewith. Applicants submit that radiographic iodine is an ion, specifically I-131.

Therefore, applicants respectfully request withdrawal of the rejections and reconsideration of the claims as amended.

Claim Objections

Claim 76 was objected to because it referred to canceled claim 74. Claim 76 has been amended to depend from claim 72.

35 U.S.C. § 103

Claims 53-61, 65-67, 80, and 84 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as being allegedly unpatentable over Foerster et al. (USP 6,228,055) in view of Stinson (USP 5,980,564). Claims 62-64 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Foerster et al. and Stinson, and further in view of Unger et al. (USP 6,231,834). Claims 75, 76, 83, and 85 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Foerster et al. and Stinson, and further in view of Ragheb et al. (USP 5,873,904). Claim 69 was rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Foerster et al. and Stinson, and further in view of Park et al. (USP 6,271,278). Claims 70 and 71 were rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Foerster et al. and Stinson, and further in view of Ersek et al. (USP 5,571,182).

Applicants respectfully argue that it would not have been obvious to combine Foerster et al. and Stinson. While Foerster et al. discloses methods and devices for marking particular locations in human tissue, Stinson discloses implantable stents for use in a vessel duct or lumen. In particular, Stinson describes an "implantable endoprosthesis [that] would be advantageous in urological, biliary, vascular, and airway applications." (Col. 2, lines 61-62). There is no motivation for one skilled in the art to combine these references.

Additionally, applicants respectfully submit that the examiner's rejection of the claims is improper under MPEP § 2307.2. This rejection of applicants' claims is equally applicable to USP 6,161,034, and therefore this rejection requires the approval of the Group Director under MPEP § 2307.2. Foerster et al. and Stinson are both prior art to USP 6,161,034. As stated in a previous amendment and response, U.S. Patent No. 6,161,034 (the Burbank '034 patent), from which the present claims were copied, was allowed over Foerster et al. More specifically, the corresponding international application WO 96/08208 A1 is listed on the face of the Burbank '034 patent, and therefore was cited and of record in the '034 patent. Applicants respectfully submit that the rejection of the claims requires the approval of the Technology Center Director, which the Action fails to indicate was obtained.

Applicants submit that the claims, as amended, are free of the cited art and are in an appropriate condition for interference with the Burbank '034 patent. Please charge Deposit Account No. **50-2862** for any fees required by this submission. If the Examiner has any questions regarding this communication, or feels that an interview might facilitate prosecution of the application, he is invited to contact the undersigned at (949) 737-2900.

Respectfully submitted,

O'MELVENY & MYERS LLP

Dated: September 7, 2004

By: Diane K Wong
Diane K. Wong
Reg. No. 54,550

JCK/DKW

34263
PATENT TRADEMARK OFFICE
O'Melveny & Myers LLP
114 Pacifica, Suite 100
Irvine, CA 92618-3315
(949) 737-2900